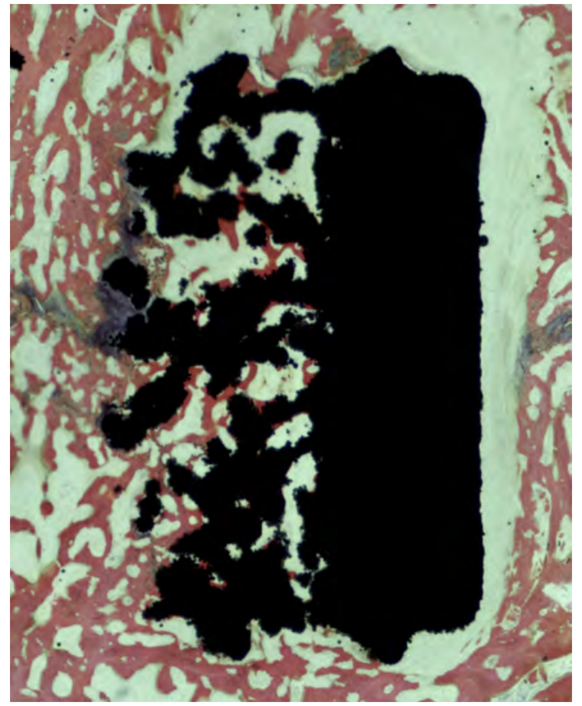
Designed for in-growth[1]

Tritanium technology has been designed for bone in-growth and biological fixation.[1]

8 weeks post-op

in an ovine model[8*]

Tritanium C Cage



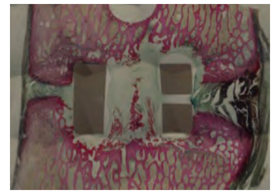
8 weeks post-op

in an ovine model[9]

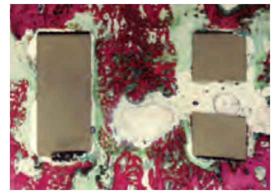
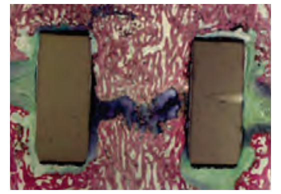
16 weeks post-op

in an ovine model[9]

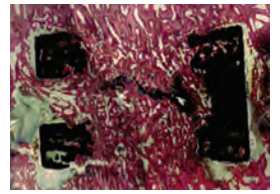
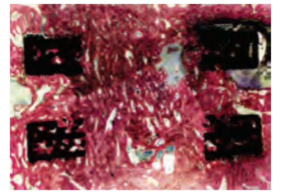
PEEK Cage




Ti Plasma Sprayed PEEK Cage

Tritanium PL Cage

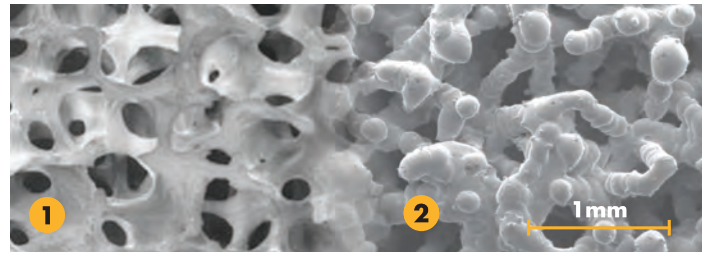
*This report reflects interim data and is subject to change until release of the final study report. Sagittal view. Correlation to human clinical outcomes has not been demonstrated or established.

1 Cancellous bone characteristics[3]

- Average pore diameter of cancellous bone = 1mm
- Average porosity of cancellous bone = 50–90%

2 Tritanium material characteristics[10†]

- Randomized pore sizing designed to mimic cancellous bone
  - Pore size range: 100–700μm
  - Mean pore size range: 400-500μm
- Interconnected pore structure from endplate to endplate
  - Mean porosity range: 55-65%



†In spinal implants

Empowered by AMagine

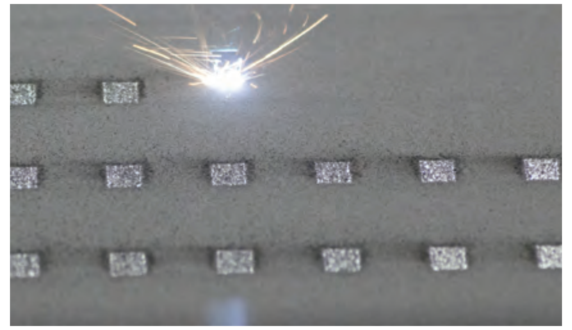
AMagine is Stryker's proprietary approach to implant creation using additive manufacturing (AM). Additive manufacturing allows us to push beyond conventional manufacturing techniques to address design complexity and achieve previously unmanufacturable geometries, but also to deliver the performance, reproducibility and quality you expect from our products.

Stryker's investment in additive manufacturing began in 2001 and, since then, Stryker has collaborated with leading universities in Ireland and the UK to industrialize 3D printing for the healthcare industry.

The AMagine Institute, Stryker's new global technology development center/hub located in Cork, Ireland, is the world's largest additive manufacturing facility for orthopaedic implants. Among the most advanced AM facilities of its kind, it is where bright ideas are transformed into exciting new implants.

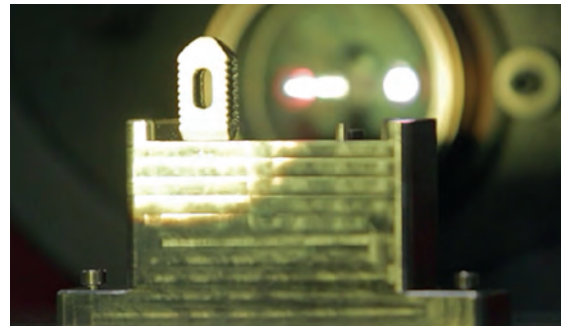
AMagine, which incorporates hundreds of quality checks per batch, enables us to design and build the Tritanium C Cage with pinpoint precision, optimizing device characteristics from pore size and porosity to shape and surgical features, for use in spinal surgery.[17]

Originally launched for hip and knee implants, Stryker's Tritanium technology has been proven in over 10 years of clinical experience with more than 300,000 orthopedic devices implanted.[17]



Built with laser precision, layer by layer[17]

AMagine Institute



Hundreds of quality checks are utilized to ensure precise design in every batch[17]

For more information please visit www.stryker.com/builttofuse

Tritanium C Cage technical data

Material	Titanium alloy
Mean porosity range	55-65%
Mean pore size range	400-500μm
Pore size range	100–700μm
Pore interconnectedness	Full, endplate to endplate
Sizing	
Footprints	12×14mm 14×17mm
Lordotic angles	6 and 10º
Heights	5–9mm

Refer to the Tritanium C surgical technique and instructions for use for complete product information.

TRICC-BR-3_15530

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stryker

Tritanium® C
Anterior Cervical Cage

Engineered for bone

Featuring Tritanium In-Growth Technology:[1]

Built to fuse™

Tritanium In-Growth **Technology**[1]

Stryker's proprietary Tritanium In-Growth Technology, used to build the Tritanium PL and C Cages, has been designed for bone in-growth[1] and biological fixation. The unique porous structure is designed to create a favorable environment for cell attachment and proliferation[2,3] and may be able to wick or retain fluid when compared to traditional titanium material.[4] Inspired by the microstructure of cancellous bone,[3] and enabled by AMagine, Stryker's proprietary approach to implant creation using additive manufacturing, this technology is deliberately designed for fusion.

Constructed to wick[4*]

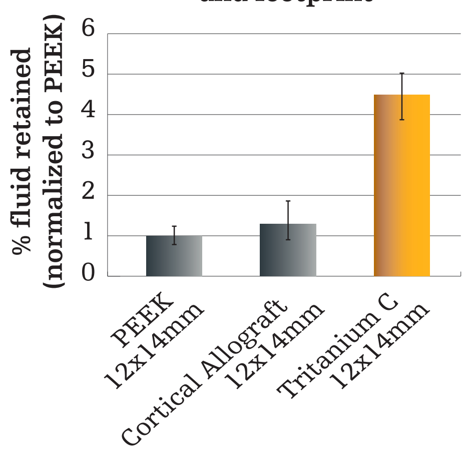
Tritanium material may be able to wick or retain fluid in comparison to traditional titanium material.[4] Tritanium material demonstrated the ability to wick fluid into the porous structure under specified conditions during an experiment. It also absorbed and held fluid inside the porous structure.[4]

- Wicking, synonymous with capillary action, allows for the distribution of nutrients throughout the cage, even against gravity[5,6]
- Wicking, synonymous with capillary action, may lead to the migration and attachment of cells[6]

The Tritanium C Cage demonstrated it absorbed 3 times more bone marrow aspirate (BMA) than allograft and 4 times more BMA than PEEK, in an in vitro study.[7]

*As compared to traditional titanium material.

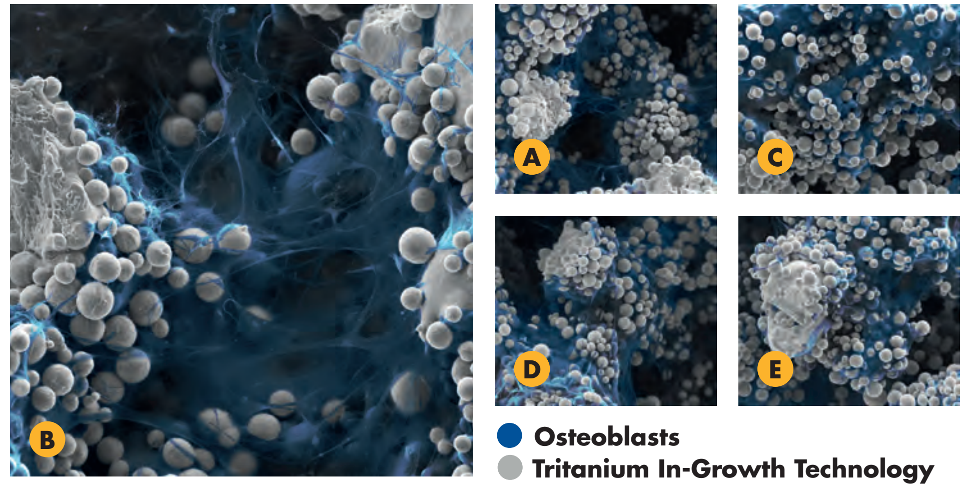
Wicking versus material and footprint[7†]



†This experiment was performed using heparinized porcine bone marrow aspirate. No correlation to human clinical outcomes has been demonstrated or established.

Designed to create a favorable environment for cells[2,3]

A coupon built with Tritanium In-Growth Technology demonstrated that osteoblasts (bone cells) **infiltrated**, **attached** to and **proliferated** on the porosity of the Tritanium technology.[2] The unique porous structure is designed to create a favorable environment for cell attachment.[2,3]



Normal human osteoblast cells were used for in-vitro cell studies. No correlation to human clinical outcomes has been demonstrated or established.

Image depicts a sample built with Tritanium Technology used for in vitro cell studies. The sample was designed to mimic a generic interbody cage with an open graft window. This is not an implantable device.

Tritanium C **Cage**

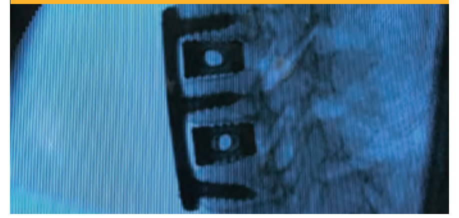
Stryker's Tritanium C Anterior Cervical Cage, is a hollow implant that consists of a unique configuration of both solid and porous structures, which are simultaneously built using Stryker's AMagine manufacturing process, applying Stryker's proprietary Tritanium In-Growth Technology.

Created to allow imaging

Designed with lateral windows, the Tritanium C Cage allows visualization on CT and X-ray.

CT

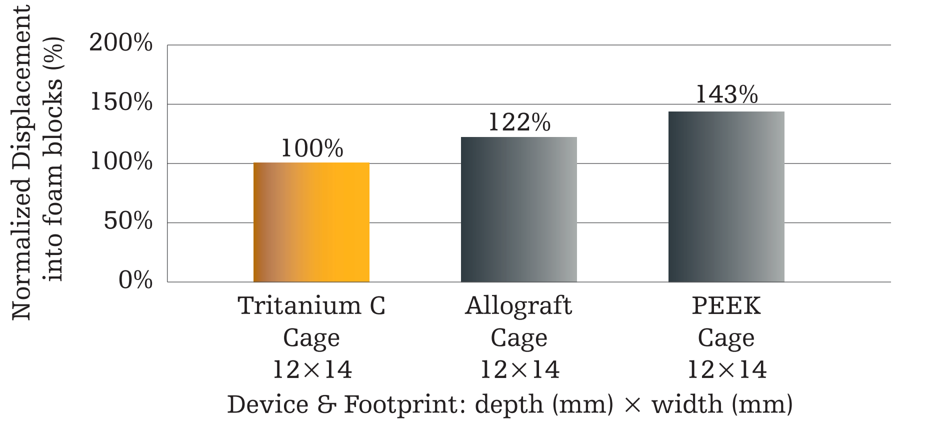
X-ray



Images taken from a cadaveric study.[11]

Developed to minimize subsidence[12]

The Tritanium C Cage demonstrated better resistance to subsidence than other commercially available cervical interbody cages constructed out of different materials.[12]

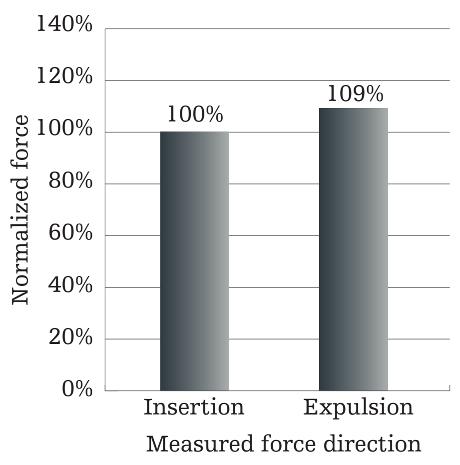


Subsidence was measured at 100N of compressive force. Testing was performed per ASTM F2267.

- Large central graft and lateral windows help further reduce the overall stiffness of the cage and allow room for bone graft to be packed inside[12]
- Porous Tritanium has an elastic modulus that falls between cancellous and cortical bone[13]
- Teeth are designed to increase surface contact with bone in order to distribute the load and minimize subsidence[13]

Shaped for stability[14,15]

The precisely angled teeth of the Tritanium C Cage are designed to allow bidirectional stability, with an expulsion force that was shown to be 9% greater than the insertion force.[14]



Insertion and expulsion testing was performed as per ASTM F04-25-02-02.

- Tritanium C cervical cages have a high coefficient of friction for initial stability[15]
- Individually sterile-packed, and available in broad range of footprints, heights and lordotic angles, the Tritanium C Cage is designed to address varying patient anatomy
  - Slopes on both the superior and inferior aspects of the cage allow hyper-lordotic options to optimize sagittal balance
  - Indicated for use in one level or two contiguous level cervical interbody fusions

"I have extensive experience with various IBD materials, such as PEEK and allograft; and as an early adopter of Tritanium PL, I have been able to compare them all. I am now a firm believer that Tritanium In-Growth Technology provides a solution that is the future of fusion procedures. **I'm excited to start using Tritanium C.**"

Dr Jeffrey J Larson*
Neurosurgeon and Tritanium PL user

	Tritanium	PEEK	Allograft
Tritanium C Cage			
Indicated/appropriate for ACDF	●	●	●
Strong, stiff, impact resistant and biocompatible	● 14, 15, 16	●	
No risk of donor infection	●	●	
No donor lot variability	●	●	
No special distribution or tracking required	●	●	
No preparation required (i.e. rinsing/soaking)	●	●	
Developed to inimize subsidence	● 12		
Tritanium In-Growth Technology			
Porous architecture reflective of bone composition	● 3		●
Modulus of elasticity similar to bone	● 13	●	●
Ability to achieve previously unmanufacturable geometries	●		
Potential to wick or retain fluid†	● 4, 7		●
Favorable material for osteoblasts	● 2		●
Enables direct bone apposition	● 8,9		●
Allows for bone integration	● 8,9		●
Manufacturing process capable of reproducible randomization	●		

*Dr. Larson is a paid consultant of Stryker. His statements represent his own opinions based on personal experience and are not necessarily those of Stryker. Individual results may vary.
† As compared to traditional titanium material

1. PROJ43909 | Tritanium technology claim support memo. **2.** RD0000053710 | Tritanium cell infiltration and attachment experiment. **3.** Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials 2005;26:5474–91. **4.** RD0000050927 | Tritanium material capillary evaluation. **5.** Hong MH, Kim YH, Ganbat D, et al. Capillary action: enrichment of retention and habitation of cells via micro-channeled scaffolds for massive bone defect regeneration. J Mater Sci: Mater Med 2014;25:1991–2001. **6.** Oh DS, Koch A, Eisig S, et al. Distinctive Capillary Action by Micro-channels in Bone-like Templates can Enhance Recruitment of Cells for Restoration of Large Bony Defect. Journal of Visualized Experiments 2015;103:e52947. **7.** RD0000053906 | Tritanium cervical competitive wicking. **8.** RD0000054287 | Tritanium-C Sheep Study 8-week Interim Report. **9.** Pre-clinical study final report, SRL 15-02/Stryker 02-15. **10.** DHF0000053171. **11.** PROJ0000054459 | Tritanium C Implant Imaging Marketing Memo. **12.** PROJ0000054457 | Tritanium C Subsidence Marketing Memo. **13.** PROJ42624 | Tritanium PL subsidence memo. **14.** PROJ0000054458 | Tritanium C Insertion and Expulsion Marketing Memo. **15.** PROJ44960 | Coefficient of friction memo.**16.** Oldani C and Dominguez A (2012). Titanium as a Biomaterial for Implants. Recent Advances in Arthroplasty. Dr. Samo Fokter (Ed.). ISBN: 978-953-307-990-5. InTech. **17.** Data on file, Stryker's Spine division.